

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Advisory Committee; Pediatric Advisory Committee; Formation of a
Pediatric Ethics Subcommittee**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

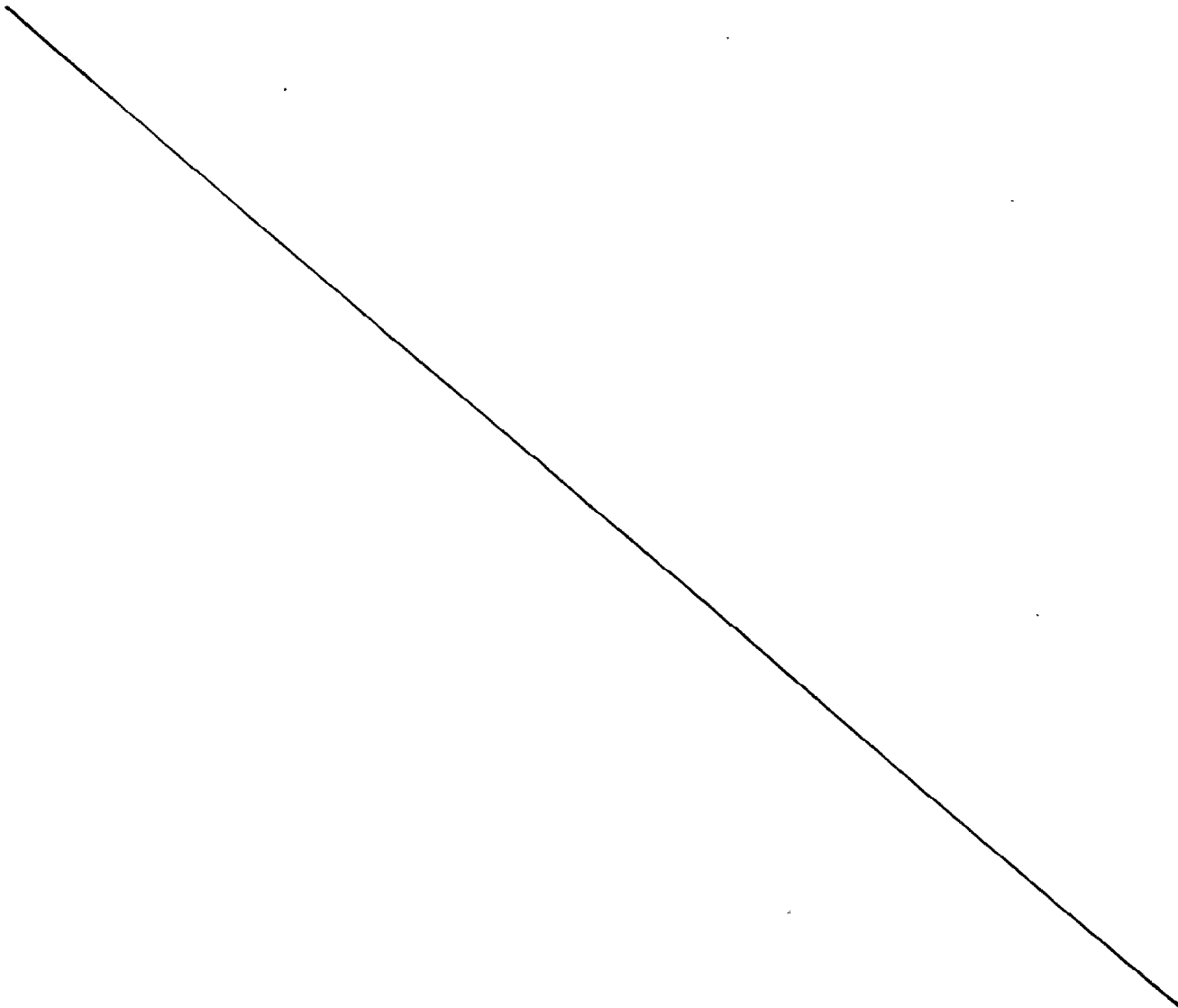
SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee of the Pediatric Advisory Committee. This subcommittee has been established to address pediatric ethical issues, as well as IRB referrals related to clinical investigations involving children as subjects and IRB referrals that involve both FDA regulated products and research involving children as subjects that is conducted or supported by the Department of Health and Human Services. The subcommittee's preliminary recommendations will be presented to the FDA Pediatric Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Jan Johannessen, Office of Science and Health Coordination (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687.

SUPPLEMENTARY INFORMATION: FDA is announcing the formation of a subcommittee of the Pediatric Advisory Committee. This subcommittee has been established to address pediatric ethical issues, as well as IRB referrals related to clinical investigations involving children as subjects as specified in § 50.54 (21 CFR 50.54) and IRB referrals that involve both FDA regulated products under § 50.54 and research involving children as subjects that is

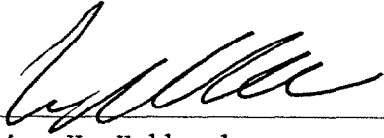
conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

The subcommittee's preliminary recommendations will be presented to the FDA Pediatric Advisory Committee. The subcommittee will meet approximately two times a year. Meetings of the subcommittee will be open to the public. All meetings will be announced in the **Federal Register** at least 15 days prior to each scheduled public meeting.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 27 2004
July 27, 2004.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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